K082836
1 of 2

ICU MEDICAL INC.
4455 Atherton Drive
Salt Lake City, Utah
(801) 264 – 1410, Phone
(801) 264 – 1755, Fax
Niloufar Samimi, Regulatory Affairs Specialist
Preparation Date: February 23, 2009

FEB 25 2009

Special 510(K) Summary of Safety and Effectiveness for the:

Trade Name: Universal Single-Use Spikes

Common Name: Set IV, Fluid transfer

Classification Name: Set IV, Fluid transfer, 21 CFR 880.5440, Class II Device

Legally Marketed Predicate Devices for Substantial Equivalence:

K964435- IV Sets- ICU Medical, Inc.

Rationale for SE:

Spikes in this submission have a same intended use and materials as predicate device. Therefore, ICU Medical believes they are substantially equivalent to the predicate device.

Description of Submitted Device:

Universal Spikes are used to build Intravascular Administration Sets which are Single Use, sterile, non- pyrogenic device and provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter inserted into a vein. Each set will be manufactured to unique specifications using dimensions, components, and configurations specified by the customer. Standard sets will also be offered. Components used in the IV sets may be either manufactured by ICU medical or purchased from other manufacturers. Components will be assembled into configurations specified by the customer and packaged.

Intended Uses of the ICU Medical Universal Single-Use Spikes:

Universal Spikes are used to build Intravascular Administration Sets which are Single Use, sterile, non- pyrogenic device and provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter inserted into a vein.

Safety and Performance:

ICU Medical Universal Single-Use Spikes conform to the requirements of published international standards as well as those FDA recognized standards and/or published guidelines prior to marketing the device. Additionally, ICU Medical's Sterility Assurance Level, (SAL) has an established history

of meeting the 10^{-6} level. The Universal Single-Use Spikes will be packaged in a way as to ensure conformity with ISO 11607-1.

Conclusion:

The materials, performance, and operational features of both the submitted device and the predicate device are substantially equivalent and are safe and effective for their intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Ms. Niloufar Samimi
Regulatory Affairs Specialist
ICU Medical, Incorporated
4455 Atherton Drive
Salt Lake City, Utah 84123

FEB 25 2009

Re: K082836
Trade/Device Name: Universal Single-Use Spikes
Regulation Number: 21 CFR 880.5440
Regulation Name: Intravascular Administration Set
Regulatory Class: II
Product Code: FMG
Dated: January 29, 2009
Received: February 2, 2009

Dear Ms. Samimi:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Anthony D. Watson for
Ginette Y. Michaud, M.D.
Acting Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K082836

Device Name:

ICU Medical Universal Single -Use Spikes

Indications for Use:

Universal Spikes are used to build Intravascular Administration Sets which are Single Use, sterile, non- pyrogenic device and provides access for the administration of fluids from a container to a patient's vascular system through the administration set's needle or catheter inserted into a vein.

Prescription Use XX (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K082836